STAR Biomarkers Research: Basic Sciences, Validation, and Applications

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Everyday, EPA makes public health decisions to manage and reduce environmental risks based on the available science in fields of toxicology, epidemiology, and other risk-oriented disciplines. Concomitantly, the Agency is marshaling and employing public health outcomes or "indicators," which provide important guidance on the effectiveness, timeliness, and impact of regulatory or risk-based decisions. In order to reduce the uncertainties in traditional risk assessment protocols and to advance the most relevant, reliable indicators, the National Center for Environmental Research (NCER), through its Science to Achieve Results (STAR) grant program, has developed a multi-year, multi-disciplinary biological markers research portfolio. Biological markers, or biomarkers, are useful for understanding the nature and extent of human exposure, risk, and intervention as they fill in important gaps in the exposure-to-disease continuum. Biomarkers, which may include chemical metabolites detectable in blood serum, DNA adducts in white blood cells, or metals in hair or nails, provide quantitative information about exposure, early biologic effect, and individual susceptibility. Ultimately, they increase our understanding of chemical transport and transformation in the body and highlight interactions at the cellular and molecular levels that lead to toxic endpoints. Further, they have provided key information on human susceptibility by identifying factors that render certain individuals or subpopulations more susceptible to the harmful effect of toxicants.

One of the goals of biomarkers research is the development and validation of tools that can be utilized in a real-world setting. It is useful to envision biomarkers research as a three-step process, beginning with the basic sciences research that first identifies a measurable property that may serve as a biomarker. Validation of that marker is the second important step, with field or clinical application as the final product. NCER has funded a variety of important work that falls into these three stages of biomarker development. Examples include 1) basic science research in molecular and genomic indicators; 2) meconium validation studies for assessing prenatal body burden of exposures to infants; 3) saliva validation studies for assessing children's exposure to pesticides; and 4) the clinical use of organophosphate metabolites in molecular epidemiology studies in the U.S. and internationally.